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RAJYA SABHA

The following report of the Joint Committee of the Houses of Parliament on the Bill further to amend the Drugs and Cosmetics Act, 1940 was presented to the Rajya Sabha on the 2nd December, 1963.

COMPOSITION OF THE JOINT COMMITTEE

MEMBERS

Rajya Sabha

1. Shri D. P. Karmarkar—*Chairman.*
2. Shri B. N. Bhargava
3. Shri Bairagi Dwibedy
4. Shri Krishna Chandra
5. Shri Kumbha Ram
6. Shri P. C. Mitra
7. Shri R. S. Khandekar
8. Dr. A. Subba Rao
9. Dr. Shrimati Seeta Parmanand
10. Dr. Jawaharlal Rohtagi.

Lok Sabha

11. Dr. R. Banerjee
12. Shri Tridib Kumar Chaudhuri
13. Dr. P. D. Gaitonde

14. Shri Shiv Charan Gupta
15. Shri Hari Vishnu Kamath
16. Shri Lahri Singh
17. Shri Braj Behari Mehrotra
18. Dr. G. S. Melkote
19. Shri R. R. Morarka
20. Shri V. C. Parashar
21. Dr. D. S. Raju
22. Shri Shivram Rango Rane
23. Dr. Saradish Roy
24. Shri A. T. Sarma
25. Dr. Sarojini Mahishi
26. Shrimati Jayaben Shah
27. Shri Krishnapal Singh
28. Dr. P. Srinivasan
29. Shri Nagendra Prasad Yadav
30. Dr. Sushila Nayar.

REPORT OF THE JOINT COMMITTEE

I, the Chairman of the Joint Committee to which the *Bill further to amend the Drugs and Cosmetics Act, 1940 was referred, having been authorised to submit the Report on their behalf, present this their Report, with the Bill as amended by the Committee annexed thereto.

2. The Bill was introduced in the Rajya Sabha on the 10th May, 1963. The motion for reference of the Bill to a Joint Committee of the Houses was moved on the 28th August, 1963, by Dr. D. S. Raju, Dpeuty Minister of Health, and was adopted by the House on the same day.

3. The Lok Sabha discussed the motion on the 12th and 13th September and concurred in it on the 18th September, 1963.

4. The message from the Lok Sabha was read out to the Rajya Sabha on the 19th September, 1963.

5. The Committee held 13 sittings in all.

6. At its first sitting held on the 20th September, 1963, the Committee decided to hear evidence from all organisations, institutions and individuals desirous of submitting memoranda to the Committee and to issue a press communique inviting memoranda for the purpose. The Committee also authorised its Chairman to decide, after examining the memoranda submitted by individuals as to who should be called to give oral evidence before the Committee.

7. One hundred and sixty-five memoranda/representations on the Bill were received by the Committee from different organisations, institutions and individuals.

8. At their second, third, fourth and fifth meetings held on the 29th, 30th and 31st October and the 1st November, 1963 respectively, the Committee heard evidence tendered by 21 organisations and one individual.

9. The Committee have decided that the whole of the evidence tendered before them be laid on the Table of the House.

*Published in Part II, Section 2 of the *Gazette of India Extraordinary*, dated the 10th May, 1963.

10. The report of the Committee was to be presented on the 18th November, 1963. The Committee was, however, granted an extension of time up to the 2nd December, 1963.

The Committee considered the Bill clause by clause at their meetings held on 2nd, 11th, 12th, 18th, 20th and 21st November, 1963.

The Committee considered the Draft Report on the 27th and the 28th November and adopted the same on the 28th November, 1963.

11. The principal changes suggested by the Committee in the Bill and the reasons therefor are set out in the succeeding paragraphs.

The Committee very carefully heard the evidence of witnesses on the point of bringing Ayurvedic and Unani drugs under the Drugs Act and the difficulties anticipated in the application of the full provisions of the Drugs Act to Ayurvedic and Unani drugs at present. The Committee agreed that since there is no standard pharmacopoeia in respect of Ayurvedic and Unani drugs at present, the provisions of the Drugs and Cosmetics Act, 1940, as they are, should not be made applicable to Ayurvedic and Unani drugs.

The Committee are of opinion that there should be a separate Act for Ayurvedic and Unani drugs. However, after careful consideration the Committee have come to the conclusion that the question of a separate Act be deferred till the time when Ayurvedic and Unani standard pharmacopoeias are ready. For the present Ayurvedic and Unani drugs should be brought under a limited control. The Commitee are of the view that apart from safeguarding the interests of the consumers, such a step would promote the growth and development of Ayurvedic and Unani drugs.

After considering the matter from all aspects, the Committee have decided that for the present it will be sufficient to ensure that—

(a) Ayurvedic and Unani drugs are prepared under sanitary conditions under the supervision of qualified and competent persons;

(b) the raw materials are identified by qualified and competent persons; and

(c) the contents of the drugs are displayed on the label.

Accordingly the Committee have proposed a separate Chapter IVA making special provisions with respect to the above matters

and have proposed much lighter punishments so as not to cause any undue hardship to the manufacturers of and dealers in Ayurvedic (including Siddha) and Unani drugs, who are being brought under the Drugs Act for the first time. The provisions of Chapter IV therefore will not apply to Ayurvedic and Unani drugs. The new sections 33I and 33J provide for punishment for offences under Chapter IVA.

The Committee also consider it necessary that the provisions of Chapter IVA should be made applicable to Government departments. The new section 33L makes necessary provisions in this behalf.

Since it has been brought to the notice of the Committee that some Ayurvedic and Unani drugs are being imported from other countries, the Committee consider that Chapter III of the Act should apply to such drugs.

Clause 2

There is a branch of Ayurveda called Siddha, having its own text-books. The Committee consider it advisable to specifically mention Siddha as part of the Ayurvedic system of medicine.

The other amendments made in the clause are consequential on the incorporation of new Chapter IVA.

Clause 3 (*New clause*)

This clause is only consequential on the incorporation of new Chapter IVA.

Clause 4 (*Original clause* 3)

Since the Committee have proposed a separate Board for Ayurvedic (including Siddha) and Unani drugs, the Committee do not consider it necessary to have the Ayurvedic and Unani systems of medicine represented in the Drugs Technical Advisory Board. Accordingly, the Committee have proposed the omission of clauses (ix), (xiv) and (xviii) of sub-section (2) of section 5 of the Act as proposed to be substituted by the original clause 3. The Committee have also proposed in that sub-section an increase in the representation of the Drugs Controllers of States from one to two and the nomination of two Government Analysts as members of the Board.

The Committee also feel that the representation provided for in clauses (xi) and (xii) of sub-section (2) of section 5 of the Act

as proposed to be substituted by the original clause 3 for teachers in Pharmacy or Pharmaceutical Chemistry or Pharmacognosy and teachers in Medicine or Therapeutics should be by election by the Executive Committees of the Pharmacy Council of India and of the Medical Council of India respectively and not by nomination by the Central Government. These clauses have been suitably amended for the purpose. The Committee further feel that under clause (xiii) of that sub-section one person may be nominated from the pharmaceutical industry alone.

Clause 5 (*New clause*)

This clause is only consequential on the incorporation of new Chapter IVA.

Clause 6 (*New clause*)

Since a separate Board has been proposed for the Ayurvedic (including Siddha) and Unani drugs, the Committee do not feel it necessary to apply the provisions of section 5 of the Act to Ayurvedic (including Siddha) and Unani drugs. The Committee further feel that for the time being there need not be any Drugs Consultative Committee to advise the Central Government, the State Governments, and the Ayurvedic and Unani Drugs Technical Advisory Board, on matters relating to Ayurvedic and Unani drugs. Accordingly, the Committee are of opinion that section 7 of the Act also need not apply to Ayurvedic (including Siddha) and Unani drugs. This clause makes provision for the purpose.

Clause 7 (*New clause*)

The Committee have incorporated a new Schedule as the First Schedule listing certain authoritative books in respect of Ayurvedic and Unani drugs. The existing Schedule has been renumbered as the Second Schedule and the amendment proposed in the clause is only consequential.

Clause 8 (*Original clause* 4)

During the evidence tendered before the Committee, it was pointed out that there may be cases where in spite of adequate care and diligence on the part of the manufacturer of the drug or the dealer thereof, it may not be possible to prevent natural decomposition of the drug within the period specified on the label of the drug within which it is to be used. The Committee feel that some protection in such cases is necessary, taking care at the same time that no allowance is given for any decomposition arising out of any negligence on the part of the manufacturer of the drug or the

importer or the dealer thereof and that the decomposition does not render the drug injurious to health. The Committee have, accordingly, proposed an explanation to the new section 9B to cover such cases.

Clause 10 (*Original clause* 6)

The changes are of a drafting nature.

Clause 11 (*New clause*)

The amendment proposed by the Committee to section 16 of the Act is only consequential on the renumbering of the existing schedule as the Second Schedule.

Clause 12 (*Original clause* 7)

A similar explanation to the one proposed by the Committee with regard to clause 8 (original clause 4) has been proposed to new section 17B also.

Clause 14 (*New clause*)

Under the scheme of the Bill the requirement of a written warrantly provided for in section 19(3) (b) of the Act is proposed to be done away with. The Committee therefore feel that there should be a specific provision in the Act whereby the dealer of the drug is obliged to disclose the name of the person from whom he acquired the drug. Such a provision, the Committee think, will enable the Inspector to locate the manufacturer of the drug and proceed against him wherever necessary. The new section 18A in this clause is to achieve this purpose.

Clause 15 (*Original clause* 9)

Under sub-section (3) of section 19 of the Act protection is given to a dealer in a drug or cosmetic from the penal provisions of the Act in the circumstances mentioned in that sub-section. This protection was proposed to be taken away by sub-clause (b) of original clause 9. It was strongly urged before the Committee that the removal of this protection would cause undue hardship to dealers in drugs as a whole. The Committee feel that necessary protection should be given to honest dealers lest it should cause undue hardship to them. Accordingly the Committee have proposed that a dealer in any drug or cosmetic shall not be liable for contravention of section 18 if he proves that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof; that he did not know and could not with reasonable diligence have ascertained that the drug or cosmetic in any way contravened the

provisions of that section and that the drug or cosmetic while in his possession was properly stored and remained in the same state as when he acquired it. For this purpose the Committee have proposed the substitution of sub-section (3) of section 19 of the Act as in sub-clause (b) of clause 15.

Clauses 16 *and* 17 (*Original clauses* 10 *and* 11).—As it is proposed to provide in clause 14 (new clause) that a dealer in any drug or cosmetic shall disclose the name of the manufacturer of the drug or cosmetic, the Committee feel that one portion of the sample of the drug or cosmetic taken from the dealer should be sent to the person from whom the dealer acquired the drug or cosmetic, so as to enable such person to defend himself in a court of law wherever necessary. These clauses have been suitably recast for this purpose.

Clause 18 (*Original clause* 12).—The Committee consider that offences relating to manufacture for sale, etc. of any drug without a valid licence as required under clause (c) of section 18 of the Act should be put on a par with offences relating to manufacture for sale, etc. of any drug deemed to be misbranded or adulterated. The Committee also feel that the discretion given to the court to award a lesser sentence of imprisonment for reasons to be recorded in writing, proposed to be taken away by the omission of the proviso to clause (a) of section 27 of the Act, should be retained. For these purposes the Committee have recast section 27 of the Act.

Clause 19 (*Original clause* 13)

The Committee consider it necessary to provide for penalty for non-disclosure of the name of the person from whom a dealer acquired the drug or cosmetic. Section 28 of the Act is proposed to be substituted for this purpose.

Clause 20 (*Original clause* 14)

As proposed by the Committee with regard to section 27 of the Act, the proviso to clause (a) of sub-section (1) of section 30 of the Act also has been retained. The Committee have proposed the necessary amendments to section 30 of the Act for increasing the quantum of maximum imprisonment.

Clause 21 (*Original clause* 15)

The Committee feel that confiscation of implements, machinery, receptacles etc. may be extended also to cases where any person manufactures for sale, sells or stocks or exhibits for sale or distributes any drug without a valid licence as required under clause (c) of section 18. Necessary provision for this purpose has been incorporated in sub-section (1) of section 31 of the Act.

Clause 23 (*New clause*)

It has been brought to the notice of the Committee that for want of a provision enabling the court during the trial of an offence against the dealer in a drug to implead the manufacturer or his agent for the distribution thereof, many manufacturers and their agents go scotfree. In order to have an effective check at all levels, the Committee consider it necessary to have a provision to the effect that if during the trial of any offence alleged to have been committed by a dealer, the court is satisfied on the evidence adduced before it that the manufacturer or his agent is also concerned with the offence the court may proceed against the manufacturer or his agent also. The new section 32A has been proposed by the Committee for this purposes.

Clause 24 (*Original clause* 17)

Minor drafting changes have been made by the Committee in clause (dd) of sub-section (2) of section 33 of the Act.

At present there is no provision in the Act for laying before Parliament the Rules made under Chapter IV of the Act. The Committee consider it necessary that all Rules made under the Act should be laid before Parliament. For this purpose the Committee have proposed the omission of sub-section (3) of section 32 of the Act and in its place a new section 38 (*vide* new clause 30) is proposed to be added by the Committee.

Clause 25 (*New clause*)

Since the Committee have proposed necessary provisions regulating the manufacture, sale etc. of Ayurvedic (including Siddha) and Unani drugs in Chapter IVA, the Committee do not consider it necessary to apply the provisions of Chapter IV to such drugs. Specific provision in this behalf has been made in the new section 33A.

Clause 30 (*New clause*)

Under this clause a new Chapter IVA making special provisions relating to Ayurvedic (including Siddha) and Unani drugs is proposed to be incorporated by the Committee. This Chapter will apply only to Ayurvedic (including Siddha) and Unani drugs. A separate Board called the Ayurvedic and Unani Drugs Technical Advisory Board is proposed to be constituted under the new section 33C. The Chairman of the Board is to be nominated by the Central Government from amongst the members of the Board.

The Committee consider that it will be sufficient for the present to regulate the manufacture for sale of any Ayurvedic (including Siddha) or Unani drug under the circumstances mentioned in clauses (a) to (f) of new section 33D. The Committee also consider that this regulation should not apply to Vaidyas and Hakims who manufacture Ayurvedic (including Siddha) or Unani drugs for the use of their own patients.

The new section 33E prohibits persons from selling or stocking or exhibiting for sale or distributing any Ayurvedic (including Siddha) or Unani drug other than that manufactured by a manufacturer licensed under Chapter IVA.

The Committee consider that the Inspectors to be appointed with respect to Ayurvedic (including Siddha) or Unani drugs should have such knowledge of Ayurvedic and Unani drugs as may be prescribed.

In view of the fact that Ayurvedic (including Siddha) and Unani drugs are being brought under control for the first time, the Committee feel that a lesser punishment may be awarded for offences under Chapter IVA. The new sections 33-I and 33-J make provisions accordingly.

The Committee also consider it necessary that the provisions of Chapter IVA should be made applicable to Government departments. The new Section 33-L makes necessary provision in this behalf.

The Committee further consider it necessary that the Central Government should be empowered to amend the First Schedule containing the list of authoritative books with respect to Ayurvedic (including Siddha) and Unani systems of medicine. The new Section 33-O makes provision for the purpose.

Clause 27 (*New clause*)

This clause renumbers the existing section 33A of the Act as section 33P. This change is only consequential.

Clause 28 (*Original clause* 18)

The Committee consider it necessary to include Chapter IVA also within the scope of the new section 34A. The clause has been amended for this purpose.

Clause 30 (*New clause*)

A new section 38 is proposed by the Committee for laying all the Rules made under the Act before Parliament.

Clause 31 (Original clause 20).

The existing Schedule has been renumbered by the Committee as the Second Schedule and before that Schedule, a new Schedule listing the names of authoritative books of Ayurvedic (including Siddha) and Unani (Tibb) systems of medicine has been inserted.

The other changes made by the Committee are only of a consequential or verbal nature.

12. During the consideration by the Committee of the penal provisions of the Act, the Committee felt that section 34 of the Act, which deals with offences by companies (including firms or other associations of individuals) dilutes the penal provisions of the Act as laid down in other sections and discriminates in favour of companies and firms as against individuals. The Committee was advised that it could not suggest any amendment to section 34 for the reason that it would be beyond the competence of the Committee to amend that section since that section is not covered by the Bill. However, the Committee recommend that section 34 should be suitably amended so as to bring it in line with the other penal provisions of the Act.

13. The Committee recommend that the Bill, as amended, be passed.

NEW DELHI;
November 28, 1963.

D. P. KARMARKAR,
Chairman of the Joint Committee.

MINUTES OF DISSENT

I

Under Clause 12 of the Amending Bill, it was proposed to bring within the scope of the Principal Act a separate category called Adulterated Drugs and also to enhance the maximum penalty of imprisonment provided for such offences to ten years in place of existing provision of five years and also to provide for the confiscation of property, apparatus etc. for the manufacture of such drugs. Moreover it proposed to do away with the power of the Court to award a sentence of imprisonment of less than one year 'for any special reason to be recorded in writing'.

The Select Committee have retained the original provision in regard to Court's power to sentence to less than one year's imprisonment but accepted the other provisions of clause 12. The majority view of the Committee is that the Legislature should not restrict the hands of the judiciary as to minimum penalty that will meet the end of justice thought it can provide maximum penalties that can be imposed for any offence. Further, there is already a restriction provided in the principal Act making it obligatory for the Court to 'record in writing' the special reason for imposing sentence of imprisonment of less than one year.

In my opinion, the original proposal to do away with the discretionary power of the Court truly reflected not only the demand of the general public but also of the Medical profession. On the 24th November last, according to an UNI report that appeared in the Searchlight of Patna, the 23rd annual Bihar State Medical Conference which was attended by about 400 delegates from all over Bihar and invitees from other States, adopted a resolution urging the Central and the State Governments to impose deterrent punishments on persons who indulge in adulteration of food and medicines. This resolution indicates that Medical men do not feel the present provisions for punishment are deterrent to stop this menace. In my opinion, merely to enhance the maximum penalty of imprisonment to ten years does not make the punishment deterrent. By retention of this discretionary power of the Court, the Committee has nullified the main objective of the Bill. It may be pointed out in this connection that generally the Courts interpret very liberally provisions of punishments provided in the Acts by Legislature which is proved from the fact that so far no Court has imposed the maximum sentence of

imprisonment of five years on any person for contravention of any provision of the existing Act. To think that the Court's hands have already been tied down by putting the condition that the Court must 'record in writing' the special reason for giving lesser sentence of imprisonment is a poor consolation. It is a common practice for a Court to record reasons for imposing lighter of deterrent punishments on any accused for any offence and as such this cannot be taken by a Court as a restriction on it to impose a lesser sentence of imprisonment. On the other hand the Court may take it that the Legislature was not serious when they provided minimum sentence of imprisonment of one year and so provided this 'escape proviso' I am afraid, if the recommendation of the Select Committee in this regard is accepted by the Parliament, most of the accused who will contravene sections 17A or 17B of the Act will get the benefit of this proviso on medical or other grounds and the penalty of minimum imprisonment of one year will be imposed in very exceptional cases. In my opinion, no sympathy should be shown to a person who is found guilty of misbranding or adulteration of drugs, even if his imprisonment for one year may endanger his life, for the simple reason that by his criminal acts he caused death or endangered so many innocent lives.

On the grounds stated above, I record my dissent on the recommendation of the Committee on clause 12 of the original Bill, so far it relates to retention of the discretionary power of the Court.

In regard to clause 14 of the original Bill, the Committee have recommended retention of the discretionary power of the Court to impose a sentence of imprisonment for less than two years. This concerns persons convicted for repeated offences under the Act. On the grounds given in regard to clause 12 of the original Bill and more strongly as it involves persons for repeated offences of the same nature, I disagree with the majority recommendation and support the proposal in the original Bill.

NEW DELHI; P. C. MITRA.
November 27, 1963.

II

We have given careful thought to the changes made by the Joint Committee. While we agree with many of them, we regret we are unable to assent to the report *in toto*. We briefly set forth hereunder some of the matters on which we disagree with the majority of members of the Committee.

We feel that, as strongly recommended by the Udupa Committee, a separate enactment for Ayurvedic and Unani systems is necessary and desirable. However a separate chapter in the present bill on the subject is just a *via media* albeit not quite satisfactory. We suggest that a separate comprehensive bill should be introduced at an early date, and further the numerous recommendations of the Udupa Committee should be effectively implemented.

We are not in agreement with the proposed clause 26 of the bill. The Central Government should not have the power of appointment of the members of the board as its chairman. The Adviser in Indigenous Systems of Medicine, Minister of Health, *ex-officio* should be the chairman of this board as the Director General of Health Services, *ex-officio* is the chairman of the other board of Allopathic system of medicine. We do not find any reason as to why the Government should reserve the power of appointing a chairman with them.

We are of the opinion—cosmetics should be brought fully within the purview of this legislation in the same manner as drugs have been.

We are of the opinion that the suitable changes in section 34 of the principal Act be made here and now. The whole purpose of enacting this legislation will be defeated if section 34 is retained as it is in the principal Act.

Penalties for repeat offences in the case of Allopathic drugs should be more deterrent, particularly for those who have been convicted of deliberate or dangerous adulteration, as also in connection with the manufacture or sale of spurious or misbranded drugs, which has been steadily on the increase in recent years. We recollect that the chairman of the Committee Shri D. P. Karmarkar, in his capacity of Minister of Health some years ago expressed his considered view that adulterators, who are murderers or potential murderers, should be awarded the capital sentence. It is also worthy of note that recently the Prime Minister, in an admirable surge of righteous indignation, suggested that wanton tree-cutting should be punishable with imprisonment for life. We are of the view that for heinous or serious cases provision should be made for more drastic penalties than those provided in the bill. Considering that the life and health of the nation is involved we are firmly of the opinion that in such cases penalties such as life term if not capital sentence, confiscation of property, deprivation of civil rights, and even flogging should have been seriously considered by the Committee.

We also want to stress that the erosion of ethical standards and moral values in public life and administration should be speedily

arrested, the social conscience re-awakened and vivified, and a revolution of national character brought about in order to finally eradicate the proliferating evil.

NEW DELHI; HARI VISHNU KAMATH
November 29, 1963. R. S. KHANDEKAR

III

It is unanimously agreed that control of the Ayurvedic and Unani medicines is desirable. But the procedure to effect the control by applying the provisions of the existing bill is wrong, harmful, impracticable and detrimental to the interests of both the Ayurvedic and Unani Systems of Medicine on the following grounds:

(1) Out of the 165 memoranda, almost all the memoranda that represent the Indigenous Systems of Medicine agree to have control on the Ayurvedic and Unani Medicines and demand a separate bill to effect the control over the Indigenous Systems of Medicine.

(2) All the telegrams and the representatives who tendered their evidence before the Committee demanded a separate bill to effect the control over the Indigenous Systems of Medicine.

(3) Almost all the members of the Joint Select Committee expressed their views to have a separate bill for controlling the Ayurvedic and Unani Medicines.

(4) The Estimates Committee and the Udupa Committee also suggested the enactment of a separate Act for Ayurvedic and Unani Medicines on the analogy of the present Act.

I therefore suggest a separate bill to control the Ayurvedic and Unani Medicines.

Even the temporary arrangement is not satisfactory on the following grounds:

(1) To have a control over the Indigenous Systems of Medicines the Udupa Committee have suggested the following as the minimum requirements:

(a) A standard Pharmacopoeia
(b) A Pharmacy Council
(c) A Drug Advisory Board
(d) A Drug Controller
(e) A Central Drug Laboratory

(f) An Inspector

(g) An Analyst.

But not even a single requirement is existing so far as Ayurvedic and Unani Medicines are concerned.

(2) The proposed Technical Advisory Board does not represent the true Ayurvedists. It is a nominated Board without having proper representation from prominent Organisations such as the All India Ayurvedic Congress and the All India Unani Tibbi Conference, and has on the other hand two representatives from the Ayurvedic Research Council which consists of such members who have no interest in Ayurveda nor are well up in it.

(3) Under the existing wording of the Bill not a single Vaidya or Hakim is protected from the operation new Section 33-D.

(4) It is harmful to apply the existing Rules on Sections 22, 23, 24, and 25 to the Ayurvedic and Unani Systems.

(5) The existing rules relating to the Hygienic conditions and the control and identification of the Ayurvedic and Unani Drugs by the non-Ayurvedic and non-Unanists is very harmful and detrimental to the interests of both the Sciences.

(6) Provisions relating to import of indigenous medicines requires thorough modification.

(7) About 80 per cent of the population is dependent on the Indigenous Systems of Medicine and the cost of the medicines consumed by them is the same as that of the Allopathic medicines. Therefore in my opinion an exclusively separate bill is necessary. It is not desirable to make the existing Act more confusing by adding these temporary provisions, when the Joint Select Committee strongly recommend separate legislation to have control over the Ayurvedic and Unani medicines.

NEW DELHI; A. T. SARMA.

November 29, 1963.

IV

I also agree with the above note of dissent (No. III).

NEW DELHI; V. C. PARASHAR.

November 30, 1963.

Bill No. XIII-B of 1963

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 1963

[AS REPORTED BY THE JOINT COMMITTEE]

[*Words side-lined or underlined indicate the amendments suggested by the Committee; asterisks indicate omissions.*]

A

BILL

further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Fourteenth Year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetics (Amendment) Act, 1963.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint, and different dates may be appointed for different provisions of this Act.

23 of 1940.

Amendment of section 3.

2. In section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act),—

(*a*) clauses (*a*) and (*aa*) shall be re-lettered as clauses (*aa*) and (*aaa*) respectively, and—

(*i*) before clause (*aa*) as so re-lettered, the following clause shall be inserted, namely:—

'(*a*) "Ayurvedic (including Siddha) or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings, mentioned in,

and processed and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic (including Siddha) and Unani (Tibb) systems of medicine, specified in the First Schedule;';

(*ii*) for clause (*aa*) as so re-lettered, the following clause shall be substituted, namely:—

'(*aa*) "the Board" means—

(*i*) in relation to Ayurvedic (including Siddha) or Unani drug, the Ayurvedic and Unani Drugs Technical Advisory Board constituted under section 33C; and

(*ii*) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;';

(*b*) in clause (*b*),—

(*i*) in sub-clause (*i*), the words "other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine" shall be omitted;

(*ii*) in sub-clause (*ii*), for the word "vermins", the word "vermin" shall be substituted;

* * *

(c) for clause (*c*), the following clause shall be substituted, namely:—

'(*c*) "Government Analyst" means—

(*i*) in relation to Ayurvedic (including Siddha) or Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

(*ii*) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;';

(d) for clause (*e*), the following clause shall be substituted, namely:—

'(*e*) "Inspector" means—

(*i*) in relation to Ayurvedic (including Siddha) or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(*ii*) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;';

(*e*) for clause (*h*), the following clause shall be substituted, namely:—

'(*h*) "patent or proprietary medicine" means a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian pharmacopoeia for the time being or in any other pharmacopoeia authorised in this behalf by the Central Government after consultation with the Board;'.

Amendment of section 4.

3. In section 4 of the principal Act, after the word and figures "Chapter IV" wherever they occur, the words, figures and letter "or Chapter IVA" shall be inserted.

Amendment of section 5.

4. In section 5 of the principal Act,—

(*a*) for sub-section (*2*), the following sub-section shall be substituted, namely:—

"(*2*) **The Board shall consist of the following members, namely:—**

(*i*) **the Director General of Health Services,** *ex officio*; **who shall be Charman;**

(*ii*) **the Drugs Controller, India,** *ex officio*;

(*iii*) **the Director of the Central Drugs Laboratory, Calcutta,** *ex officio*;

(*iv*) **the Director of the Central Research Institute, Kasauli,** *ex officio*;

(*v*) **the Director of the Indian Veterinary Research Institute, Izatnagar,** *ex officio*;

(*vi*) **the President of the Medical Council of India,** *ex officio*;

(*vii*) **the President of the Pharmacy Council of India,** *ex officio*;

(*viii*) **the Director of the Central Drug Research Institute, Lucknow,** *ex officio*;

* * * * *

(*ix*) **two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;**

(*x*) **one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto;**

(*xi*) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

(*xii*) one person to be nominated by the Central Government from the pharmaceutical industry* * *;

* * * *

(*xiii*) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(*xiv*) one person to be elected by the Central Council of the Indian Medical Association;

(*xv*) one person to be elected by the Council of the Indian Pharmaceutical Association;

(*xvi*) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government;

* * * *

(*b*) in sub-section (*3*), for the proviso, the following proviso shall be substituted, namely:—

"Provided that the person nominated or elected, as the case may be, under clause (*ix*) or clause (*x*) or clause (*xi*) or clause (*xvi*) of sub-section (*2*) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.".

Amendment of section 6.

5. In section 6 of the principal Act, in clause (*d*) of sub-section (*2*), for the words and figures "under Chapter IV", the words, figures and letter "under Chapter IV or Chapter IVA" shall be substituted.

Insertion of new section 7A.

6. In Chapter II of the principal Act, after section 7, the following section shall be inserted, namely:—

Sections 5 and 7 not to apply to Ayurvedic (including Siddha) or Unani drugs.

"7A. Nothing contained in sections 5 and 7 shall apply to Ayurvedic (including Siddha) or Unani drugs.".

Amendment of section 8.

7. In section 8 of the principal Act, for the words "the Schedule" wherever they occur, the words "the Second Schedule" shall be substituted.

Insertion of new section 9B.

8. After section 9A of the principal Act, the following section shall be inserted, namely:—

Adulterated drugs.

"9B. For the purposes of this Chapter, a drug shall be deemed to be adulterated—

(*a*) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(*c*) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(*d*) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(*e*) if any substance has been—

(*i*) mixed or packed therewith so as to reduce its quality or strength; or

(*ii*) substituted wholly or in part therefor.

Explanation.—For the purpose of clause (*a*), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug within the period, if any, specified on the label of the drug within which the drug is to be used:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the importer or the dealer thereof and that it does not render the drug injurious to health.".

Amendment of section 10.

9. In section 10 of the principal Act, after clause (*b*), the following clause shall be inserted, namely:—

"(*bb*) any adulterated drug;".

Amendment of section 12.

10. In section 12 of the principal Act, in sub-section (*2*), after clause (*c*), the following clause shall be inserted, namely:—

"(*cc*) prescribe under clause (*d*) of section 9B the colour or colours which a drug may bear or contain for purposes of colouring;".

Amendment of section 16.

11. In section 16 of the principal Act, for the words "the Schedule" wherever they occur, the words "the Second Schedule" shall be substituted.

Insertion of new section 17 B. Adulterated drugs.

12. After section 17A of the principal Act, the following section shall be inserted, namely:—

"17B. For the purposes of this Chapter a drug shall be deemed to be adulterated—

(*a*) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(*c*) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(*d*) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(*e*) if any substance has been—

(*i*) mixed or packed therewith so as to reduce its quality or strength; or

(*ii*) substituted wholly or in part therefor.

Explanation.—For the purpose of clause (*a*), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug within the period, if any, specified on the label of the drug within which the drug is to be used:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the dealer thereof and that it does not render the drug injurious to health.".

Amendment of section 18.

13. In section 18 of the principal Act, in clause (*a*), after sub-clause (*ii*), the following sub-clause shall be inserted, namely:—

"(*iia*) any adulterated drug;".

Insertion of new section 18A. Disclosure of the name of the manufacturer, etc.

14. After section 18 of the principal Act, the following section shall be inserted, namely:—

"18A. Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.".

15. In section 19 of the principal Act,— Amendment of section 19.

(*a*) in sub-section (2),—

(*i*) for the words and figures "For the purposes of section 18 a drug or cosmetic shall not be deemed to be misbranded or to be below standard quality", the words and figures "For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality" shall be substituted;

(*ii*) clause (*aa*) shall be omitted;

(*b*) for sub-section (3), the following sub-section shall be substituted, namely:—

"(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—

(*a*) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(*b*) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(*c*) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.".

16. In section 23 of the principal Act, for clause (*iii*) of sub-section (4), the following clause shall be substituted, namely:— Amendment of section 23.

"(*iii*) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.".

17. In section 25 of the principal Act,— Amendment of section 25.

(*a*) in sub-section (2), for the words, brackets and figures "and another copy to the warrantor, if any, named under the proviso to sub-section (3) of section 19", the words, figures and letter "and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A" shall be substituted;

(*b*) in sub-section (3), for the words "or the said warrantor", the words, figures and letter "or the person whose name, address

and other particulars have been disclosed under section 18A" shall be substituted.

Substitution of section 27.

18. For section 27 of the principal Act, the following section shall be substituted, namely:—

Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.

"27. Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale or distributes—

(*a*) any drug—

(*i*) deemed to be misbranded under clause (*a*), clause (*b*), clause (*c*), clause (*d*), clause (*f*) or clause (*g*) of section 17 or adulterated under section 17B; or

(*ii*) without a valid licence as required under clause (*c*) of section 18,

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to ten years and shall also be liable to fine:

Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of imprisonment of less than one year;

(*b*) any drug other than a drug referred to in clause (*a*) in contravention of any of the provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to three years, or with fine, or with both.".

Substitution of section 28.

19. For section 28 of the principal Act, the following section shall be substituted, namely:—

Penalty for non-disclosure of the name of the manufacturer, etc.

"28. Whoever contravenes the provisions of section 18A shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to five hundred rupees, or with both.".

Amendment of section 30.

20. In section 30 of the principal Act,—

(*a*) in sub-section (*1*), for the words "five years" wherever they occur, the words "ten years" shall be substituted;

(*b*) in sub-section (*2*),—

(*i*) the words and figures "section 28 or" shall be omitted;

(*ii*) for the words "two years", the words "ten years" shall be substituted.

Amendment of section 31.

21. In section 31 of the principal Act,—

(*a*) in sub-section (*1*), the following shall be added at the end, namely:—

"and if such contravention is in respect of—

(*i*) manufacture of any drug deemed to be misbranded under clause (*a*), clause (*b*), clause (*c*), clause (*d*), clause (*f*) or clause (*g*) of section 17 or adulterated under section 17B; or

(*ii*) manufacture for sale, or sale, or stocking or exhibiting for sale, or distribution of any drug without a valid licence as required under clause (*c*) of section 18,

any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation";

(*b*) in sub-section (*2*), for the words "or is a misbranded drug", the words "or is a misbranded or adulterated drug" shall be substituted.

Insertion of new section 31A.

22. After section 31 of the principal Act, the following section shall be inserted, namely:—

Application of provisions to Government departments.

"31A. The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs by any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person.".

Insertion of new section 32A.

23. After section 32 of the principal Act, the following section shall be inserted, namely:—

Power of Court to implead the manufacturer, etc.

"32A. Where, at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then, the Court may, notwithstanding anything contained in sub-section (*1*) of section 351 of the Code of Criminal Procedure, 1898, proceed against him as

5 of 1898.

though a prosecution had been instituted against him under section 32.".

Amendment of section 33.

24. In section 33 of the principal Act,—

(*i*) in sub-section (*2*),—

(*a*) after clause (*d*), the following clause shall be inserted, namely:—

"(*dd*) prescribe under clause (*d*) of section 17B the colour or colours which a drug may bear or contain for purposes of colouring;";

(*b*) clause (*m*) shall be omitted;

(*c*) for clause (*p*), the following clause shall be substituted, namely:—

"(*p*) specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 31; and";

(*ii*) sub-section (*3*) shall be omitted.

Insertion of new section 33A.

25. In Chapter IV of the principal Act, after section 33, the following section shall be inserted, namely:—

Chapter not to apply to Ayurvedic (including Siddha) or Unani drugs.

"33A. Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to Ayurvedic (including Siddha) or Unani drugs.".

Insertion of new Chapter IVA.

26. After Chapter IV of the principal Act, the following Chapter shall be inserted, namely:—

'CHAPTER IVA

PROVISIONS RELATING TO AYURVEDIC (INCLUDING SIDDHA) AND UNANI DRUGS

Application of Chapter IV A.

33B. This Chapter shall apply only to Ayurvedic (including Siddha) and Unani drugs.

Ayurvedic and Unani Drugs Technical Advisory Board.

33C. (*1*) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the Ayurvedic and Unani Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

(2) The Board shall consist of the following members, namely :—

(*i*) the Director General of Health Services, *ex officio* ;

(*ii*) the Drugs Controller, India, *ex officio* ;

(*iii*) the Adviser in indigenous systems of Medicine, Minitsry of Health, *ex officio* ;

(*iv*) the Director of the Central Drugs Laboratory, Calcutta, *ex officio* ;

(*v*) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government;

(*vi*) one Pharmacognocist to be nominated by the Central Government;

(*vii*) one Phyto-chemist to be nominated by the Central Government;

(*viii*) two persons to be nominated by the Central Government from among members of the Central Council of Ayurvedic Research;

(*ix*) one teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government;

(*x*) one teacher in IL-MUL-ADVIA and TAKLIS-WA-DAWASAZI, to be nominated by the Central Government;

(*xi*) two persons, one each to represent the Ayurvedic (including Siddha) and Unani drug industry, to be nominated by the Central Government;

(*xii*) two persons, one each from among the practitioners of Ayurvedic (including Siddha) and Unani systems of medicine, to be nominated by the Central Government.

(3) The Central Government shall appoint a member of the Board as its Chairman.

(4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination.

(5) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

Prohibition of manufacture for sale of Ayurvedic (including Siddha) and Unani drugs.

33D. From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf, manufacture for sale any Ayurvedic (including Siddha) or Unani, drug—

(*a*) except under prescribed hygienic conditions;

(*b*) except under the supervision of a person having the prescribed qualifications;

(*c*) except under and in accordance with the conditions of a licence issued for such purpose under this Chapter;

(*d*) unless the raw materials used in the preparation of such drug are genuine and are properly identified;

(*e*) unless such drug is labelled with the true list of all the ingredients contained in it and with such other particulars as may be prescribed; and

(*f*) in contravention of any of the provisions of this Chapter or any rule made thereunder:

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture such drugs for the use of their own patients:

Provided further that nothing in clauses (*a*), (*b*) and (*c*) shall apply to the manufacture, subject to prescribed conditions, of small quantities of any such drug for the purpose of examination, test or analysis.

Restriction on sale, etc., of Ayurvedic (including Siddha) and Unani drugs.

33E. From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf, sell, or stock or exhibit for sale, or distribute, any Ayurvedic (including Siddha) or Unani drug other than that manufactured by a manufacturer licensed under this Chapter.

Government Analysts.

33F. (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

Inspectors.

33G. (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

45 of 1860.

Application of provisions of sections 22, 23, 24 and 25.

33H. The provisions of sections 22, 23, 24 and 25 and the rules, if any, made thereunder shall, so far as may be, apply in relation to an Inspector and a Government Analyst appointed under this Chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the

modification that the references to "drug" in the said sections, shall be construed as references to "Ayurvedic (including Siddha) or Unani drug".

Sale, etc., of Ayurvedic (including Siddha) and Unani drugs in contravention of this Chapter.

33I. Whoever contravenes the provisions of section 33D or section 33E or section 24 as applied by section 33H or any rule made under this Chapter shall be punishable with imprisonment for a term which may extend to three months, or with fine which may extend to five hundred rupees, or with both.

Penalty for subsequent offences.

33J. Whoever, having been convicted of an offence under section 33D or section 33E is again convicted of an offence under the said section shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.

Confiscation.

33K. Where any person has been convicted under this Chapter, the stock of the Ayurvedic (including Siddha) or Unani drug, in respect of which the contravention has been made, shall be liable to confiscation.

Application of provisions to Government departments.

33L. The provisions of this Chapter except those contained in section 33K shall apply in relation to the manufacture for sale, sale, or distribution of any Ayurvedic (including Siddha) or Unani drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person.

Cognizance of offences.

33M. (*1*) No prosecution under this Chapter shall be instituted except by an Inspector.

(*2*) No Court inferior to that of a Presidency Magistrate or of a Magistrate of the first class shall try an offence punishable under this Chapter.

Power of Central Government to make rules.

33N. (*1*) The Central Government may, after consultation with the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter;

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may,—

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic (including Siddha) or Unani drugs;

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic (including Siddha) or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of Ayurvedic (including Siddha) or Unani drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

(f) regulate the mode of labelling packed Ayurvedic (including Siddha) or Unani drugs and prescribe the matters which shall or shall not be included in such labels;

(g) prescribe the conditions subject to which small quantities of Ayurvedic (including Siddha) or Unani drugs may be manufactured for the purpose of examination, test or analysis; and

(h) any other matter which is to be or may be prescribed under this Chapter.

Power to amend First Schedule.

330. The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.'.

Amendment of section 33A.

27. Section 33A of the principal Act shall be re-numbered as section 33P.

Insertion of new section 34A.

28. After section 34 of the principal Act, the following section shall be inserted, namely:—

Offences by Government departments

"34A. Where an offence under Chapter IV or Chapter IVA has been committed by any department of Government, such authority as is specified by the Central Government to be in-charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided in Chapter IV or Chapter IVA, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.".

Amendment of section 36.

29. In section 36 of the principal Act, the words and figures "section 32 of" shall be omitted.

Insertion of new section 38.

30. After section 37 of the principal Act, the following section shall be inserted, namely:—

Rules to be laid before Parliament.

"38. Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".

Substitution of Schedule.

31. For the Schedule to the principal Act, the following Schedules shall be substituted, namely:—

"THE FIRST SCHEDULE

[*See* section 3(*a*)]

A.—AYURVEDIC (INCLUDING SIDDHA) SYSTEM

Serial No.	Name of book
	Ayurveda
1.	Arogya Kalpadruma
2.	Arka Prakasha
3.	Arya Bhishak
4.	Ashtanga Hridaya
5.	Ashtanga Samgraha
6.	Ayurveda Kalpadruma
7.	Ayurveda Prakasha
8.	Ayurveda Samgraha
9.	Bhaishajya Ratnavali
10.	Bharat Bhaishajya Ratnakara
11.	Bhava Prakasha
12.	Brihat Nighantu Ratnakara
13.	Charaka Samhita
14.	Chakra Datta
15.	Gada Nigraha
16.	Kupi Pakva Rasayana
17.	Nighantu Ratnakara
18.	Rasa Chandanshu
19.	Rasa Raja Sundara
20.	Rasaratna Samuchaya
21.	Rasatantra Sara Siddha Prayoga Samgraha
22.	Rasa Tarangini
23.	Rasa Yoga Sagara
24.	Rasa Yoga Ratnakara
25.	Rasa Yoga Samgraha
26.	Rasendra Sara Samgraha

Serial No.	Name of book
27.	Rasa Pradipika
28.	Sahasrayoga
29.	Sarvaroga Chikitsa Ratnam
30.	Sarvayoga Chikitsa Ratnam
31.	Sharangadhara Samhita
32.	Siddha Bhaishajya Manimala
33.	Siddha Yoga Samgraha
34.	Sushruta Samhita
35.	Vaidya Chintamani
36.	Vaidyaka Shabda Sindu
37.	Vaidyaka Chikitsa Sara
38.	Vaidya Jiwan
39.	Basava Rajeeyam
40.	Yoga Ratnakara
41.	Yoga Tarangini
42.	Yoga Chintamani
43.	Kashyapasamhita
44.	Bhelasamhita
45.	Vishwanathachikitsa
46.	Vrindachikitsa
47.	Ayurvedachintamani
48.	Abhinavachintamani
49.	Ayurveda-ratnakar
50.	Yogaratnasangraha
51.	Rasamrita
52.	Dravyagunanighantu
53.	Rasamanjari
54.	Bangasena
	Siddha
55.	Siddha Vaidya Thirattu
56.	Therayar Maha Karisal
57.	Brahma Muni Karukkadai (300)
58.	Bhogar (700)
59.	Pulippani (500)
60.	Agasthiyar Paripuranam (400)
61.	Therayar Yamagam
62.	Agasthiyar Chenduram (300)
63.	Agasthiyar (1500)
64.	Athmarakshamrutham
65.	Agasthiyar Pin (80)
66.	Agasthiyar Rathna Churukkam
67.	Therayar Karisal (300)

Serial No.	Name of book
68.	Veeramamuni Nasa Kandam
69.	Agasthiyar (600)
70.	Agasthiyar Kanma Soothiram
71.	18 Siddhar's Chillarai Kovai
72.	Yogi Vatha Kaviyam
73.	Therayar Tharu
74.	Agasthiyar Vaidya Kaviyam (1500)
75.	Bala Vagadam
76.	Chimittu Rathna (Rathna) Churukkam
77.	Nagamuni (200)
78.	Agasthiyar Chillarai Kovai
79.	Chikicha Rathna Deepam
80.	Agasthiyar Nayana Vidhi
81.	Yugi Karisal (151)
82.	Agasthiyar Vallathi (600)
83.	Therayar Thalia Varkam

B.—UNANI (TIBB) SYSTEM

Serial No.	Name of book
1.	Karabadin Qadri
2.	Karabadin Kabir
3.	Karabadin Azam
4.	Ilaj-ul-Amraz
5.	Al Karabadin
6.	Biaz Kabir Vol. II
7.	Karabadin Jadid
8.	Kitab-ul-Taklis
9.	Sanat-ul-Taklis
10.	Mifta-ul-Khazain
11.	Madan-ul-Aksir
12.	Makhzan-ul-murabhat.

THE SECOND SCHEDULE

(*See* sections 8 and 16)

STANDARDS TO BE COMPLIED WITH BY IMPORTED DRUGS AND BY DRUGS MANUFACTURED FOR SALE, SOLD, STOCKED OR EXHIBITED FOR SALE OR DISTRIBUTED

Class of drug	Standard to be complied with
1. Patent or proprietary medicines.	The formula or list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed.
2. Substances commonly known as vaccines, sera, toxine, toxoids, antitoxins, and antigens and biological products of such nature.	The standards maintained at the International Laboratory for Biological Standards, Stantans Seruminstitut, Copenhagen and such further standards of strength, quality and purity as may be prescribed.
3. Vitamins, hormones and analogous products.	The standards maintained at the International Laboratory for Biological Standards, National Institute for Medical Research, London, and such further standards of strength, quality and purity as may be prescribed.
4. Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals.	Such standards as may be prescribed.
5. Other drugs:	
(*a*) Drugs included in the Indian Pharmacopoeia.	Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being and such other standards as may be prescribed.
(*b*) Drugs not included in the Indian Pharmacopoeia but which are included in any Pharmacopoeia of any other country.	Standards of identity, purity and strength specified for the drugs in the edition of such pharmacopoeia for the time being and such other standards as may be prescribed.

Transitory provision.

32. Until the constitution of the Drugs Technical Advisory Board under section 5 of the principal Act as amended by this Act, the Drugs Technical Advisory Board constituted under section 5 of the principal Act and functioning immediately before the commencement of this Act shall be deemed to be the Drugs Technical Advisory Board constituted under section 5 of the principal Act as amended by this Act and shall continue to function as if this Act had not been passed.

B. N. BANERJEE,
Secretary.

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